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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,133	07/11/2003	Lixiong Li	ARA-US-PI	4427
44702	7590	05/22/2006		
OSTRAGER CHONG FLAHERTY & BROITMAN PC 250 PARK AVENUE, SUITE 825 NEW YORK, NY 10177			EXAMINER SAVAGE, MATTHEW O	
			ART UNIT	PAPER NUMBER

1724

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

✓

Interview Summary	Application No.	Applicant(s)	
	10/618,133	LI ET AL.	
	Examiner	Art Unit	
	Matthew O. Savage	1724	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Matthew O. Savage. (3) Roberto Gomez.
 (2) Manette Dennis. (4) ____.

Date of Interview: 18 May 2006.

Type: a) ☒ Telephonic b) ☐ Video Conference
 c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☒ Yes e) ☐ No.

If Yes, brief description: Proposed amendment filed via facsimile on 5-17-06.

Claim(s) discussed: 24 and 78.

Identification of prior art discussed: None.

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

M. Savage
 Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: It was agreed that amended claims 24 and 78 in the proposed amendment would be allowable if officially filed. The examiner noted that the period after "processor" on line 16 of proposed amended claim 24 should be changed to a semicolon. The examiner agreed to withdraw the drawing objection concerning the "spring-loaded adjustable pressure relief valve" since such a structure was well known in the art. The examiner agreed to withdraw the new matter rejection concerning amended FIG. 3 since the relief valve configuration having a single inlet and outlet had been shown in original FIG. 11A. The following corrections to the specification were discussed: change "5" to --5A-- on line 9 of page 23; change "53" to --55-- on line 19 of page 23; change "372" to --374-- on line 18 of page 35 .

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FACSIMILE COVER PAGE

DATE: May 17, 2006

TO: United States Patent and Trademark Office
ATTN: Examiner Matthew O. Savage
FAX NO. 571-273-1146

FROM: Manette Dennis

RE: U.S. Pat. Appl. Ser. No. 10/618,133
Art Unit 1724
Atty. Docket: ARA-US-P1

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May 17, 2006

BY FACSIMILE ONLY

Examiner Matthew O. Savage
U.S. Patent and Trademark Office
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

U.S. Patent Appl. Ser. No. 10/618,133
For: APPARATUS AND METHOD FOR CONTINUOUS
DEPYROGENTATION AND PRODUCTION OF
STERILE WATER FOR INJECTION
Filed: July 11, 2003
Our Ref: ARA-US-P1

Dear Examiner Savage:

We are patent counsel for Applicants in the above captioned matter. Pursuant to your telephone conversation with Roberto L. Gomez of our office this morning, attached are our proposed amendments in response to the final Office Action mailed on February 22, 2006 ("Office Action").

Amendments to the Claims

Claims 1, 23, and 39-44 have been cancelled.

Claims 74-77 have been withdrawn.

Claim 78 has been amended as suggested by the Examiner (Office Action, page 11, par. 2). We used the word "comprising a fluid heater" rather than the term "including a fluid heater" as suggested by the Examiner.

Claims 2-5, 7, 9-11, 16-18, 45, 48 have been amended to depend from claim 78. In addition, claims 17 and 18 have been further amended to recite a "controller for controlling the fluid heater". Claim 45 has been further amended to recite that the fluid heater is a hot gas heater.

Claim 24 has been amended to include claims 1 and 23 as suggested by the Examiner (Office Action, page 12, par. 2). Claims 31 and 32 have been amended to depend from claim 24.

OSTRAGER CHONG FLAHERTY & BROITMAN P.C.

Examiner Mathew O. Savage
May 17, 2006
Page 2

Objections to Drawings

On page 2, par. 2 of the Office Action, the drawings were objected to under 37 CFR 1.83(a) as not showing the spring-loaded adjustable pressure relief valve recited in claim 12 (actually claim 9). We direct Examiner's attention to FIG. 3 showing pressure relief valve 32 and the specification which states:

The pressure relief valve 32 is interposed between the flow splitter 26 and the first flow restrictor 28. The pressure relief valve is designed to open when the pressure of the fluid in the recirculating loop reaches a specified pressure and to close when the fluid pressure falls below the specified pressure. Preferably, the pressure relief valve is an adjustable spring-loaded type pressure relief valve.

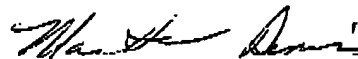
Specification at page 16, line 19-23 (underlining added)

On page 3, par. 1-2 of the Office Action, the Examiner objected to the proposed amendment of FIG. 3 on the ground that the added material (i.e., a pressure relief valve having a single inlet and single outlet) was not supported by the original disclosure. Later on in par. 4, the Examiner stated that the proposed amendment to FIG. 3 outlining the process control system 22 was approved.

However, Applicants did not propose any amendment to process control system 22 in FIG. 3. We also noted that on the Replacement Sheet 3/17, the Examiner approved the proposed amendment in FIG. 3 regarding the pressure relief valve. We have attached a copy of Replacement Sheet 3/17. We ask if the Examiner could please clarify the status of the Applicants' proposed amendment to the pressure relief valve 32 in FIG. 3.

We thank the Examiner for his kind consideration and look forward to hearing his comments.

Respectfully,



Manette Dennis
Reg. No. 30,623

Enclosures

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May 17, 2006

**PROPOSED AMENDMENTS TO THE CLAIMS
IN RESPONSE TO THE FINAL OFFICE ACTION**

1. (cancelled)
2. (currently amended) The fluid processor of claim [[1]] 78, wherein the process control system maintains the pressure of the fluid in the processor assembly at least about the saturation point of the fluid at a predetermined temperature.
3. (currently amended) The fluid processor of claim [[1]] 78, wherein the flow splitter is a filtration device.
4. (currently amended) The fluid processor of claim [[1]] 78, wherein the flow splitter is a reverse osmosis device.
5. (currently amended) The fluid processor of claim [[1]] 78, wherein at least one flow restrictor is a fixed setting flow restrictor.
6. (original) The fluid processor of claim 5, wherein the fixed setting flow restrictor is a fixed length capillary tube.
7. (withdrawn-currently amended) The fluid processor of claim [[1]] 78, wherein at least one flow restrictor is an adjustable setting flow restrictor.
8. (withdrawn) The fluid processor of claim 7, wherein the adjustable setting flow restrictor is a metering valve.
9. (currently amended) The fluid processor of claim [[1]] 78, wherein ~~the~~ at least one pressure relief valve is a spring-loaded adjustable pressure relief valve.
10. (currently amended) The fluid processor of claim [[1]] 78, wherein the fluid processor further comprises a check valve disposed upstream of the processor assembly.

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11. (currently amended) The fluid processor of claim [[1]] 78, further comprising a treatment assembly comprising a prefilter disposed upstream of the processor assembly
12. (original) The fluid processor of claim 11, wherein the treatment assembly further comprises a reverse osmosis device disposed downstream of the prefilter.
13. (original) The fluid processor of claim 11, wherein the treatment assembly further comprises a RODI apparatus disposed between the prefilter and the processor assembly, the RODI apparatus comprising a reverse osmosis device and an ion exchange device.
14. (withdrawn) The fluid processor of claim 11, wherein the treatment assembly further comprises a RODI apparatus disposed downstream of the processor assembly, the RODI apparatus comprising a reverse osmosis device and an ion exchange device.
15. (withdrawn) The fluid processor of claim 11, wherein the treatment assembly further comprises a RODI apparatus comprising: an ion exchange device disposed between the prefilter and processor assembly; and a reverse osmosis device disposed downstream of the processor assembly.
16. (currently amended) The fluid processor of claim [[1]] 78, wherein fluid processor processes feed water to produce sterile water for injection.
17. (currently amended) The fluid processor of claim [[1]] 78, further comprising:
 - a temperature sensor for measuring the temperature of the fluid in the processor assembly; and
 - a means controller for controlling the ~~temperature of the fluid in the processor assembly~~ fluid heater.
18. (currently amended) The fluid processor of claim [[1]] 78, further comprising an

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electronic control system for controlling the fluid processor, the electronic control system comprising:

a touch screen interface for providing readouts and operator input; and
 a programmable logic controller for managing the electronic control system, the programmable logic controller comprising a main control circuit and a central processing unit and further, wherein the programmable logic controller is interfaced with a temperature sensor, a pressure transducer, ~~a means for controlling the temperature of the fluid in the processor assembly~~ controller for controlling the fluid heater, and a pump controller.

19. (original) The fluid processor of claim 18, wherein the programmable logic controller is further interfaced with an endotoxin sensor having a signal conditioner, a flow rate meter having a flow sensor, and a conductivity meter having a conductivity cell.

20. (withdrawn) The fluid processor of claim 19, wherein the endotoxin sensor, flow sensor and conductivity cell are disposed downstream of the processor assembly along a discharge line.

21. (previously presented) The fluid processor of claim 19, wherein the flow sensor and conductivity cell are disposed downstream of the processor assembly along a divert line.

22. (original) The fluid processor of claim 19, wherein the endotoxin sensor, flow sensor and conductivity cell are disposed along a divert line.

23. (cancelled)

24. (currently amended) ~~[[The]] A fluid processor of claim 23, wherein the fluid processor further comprises~~ comprising:

a pump for drawing a fluid from a fluid source through a fluid inlet and

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pressurizing the fluid:

a processor assembly for processing the fluid from the pump, the processor assembly comprising:

a heat exchanger for recovering thermal energy;

a reactor for processing a fluid by heating;

and a heater for heating the reactor;

a process control system comprising: a flow splitter disposed between the pump and the processor assembly for diverting a portion of the fluid from the pump, a first flow restrictor for receiving the diverted fluid and directing the diverted fluid to the fluid inlet, a pressure relief valve disposed between the first flow restrictor and the flow splitter, and a second flow restrictor disposed downstream of the processor assembly, wherein the flow splitter, first flow restrictor, second flow restrictor and pressure relief valve are constructed and arranged to coact with each other to control the pressure and flow rate of the fluid in the fluid processor.

a sanitization assembly comprising:

an isolation valve disposed immediately downstream of the fluid inlet;

a drain valve disposed at the lowest point of the fluid processor and between the pump and the processor assembly; and

a startup loop assembly comprising:

a first fluid path running from the isolation valve to the reactor;

a second fluid path running from the isolation valve to the pump;

a startup flow restrictor disposed immediately downstream of the isolation valve and positioned along the first fluid path; and

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a four-way valve disposed immediately downstream of the startup
flow restrictor and the pump, the four-way valve-having

a first connection for receiving fluid from the startup flow
restrictor,

a second connection for directing fluid from the startup
flow restrictor to the reactor,

a third connection for receiving fluid from the pump, and

a fourth connection for directing the fluid from the pump to
the heat exchanger, and further,

wherein the four-way valve has a startup position for
directing fluid from the startup flow restrictor to the reactor through the
first and second connection and a normal position for directing the fluid
from the pump to the heat exchanger through the third and fourth
connection.

25. (original) The fluid processor of claim 24, wherein startup flow restrictor is a fixed
setting flow restrictor.

26. (original) The fluid processor of claim 24, wherein the startup flow restrictor is an
adjustable setting flow restrictor.

27. (previously presented) A method for sanitizing the fluid processor of claim 24 during
startup, the method comprising:

connecting the fluid inlet to the fluid source wherein the fluid source has a line
pressure of not less than about 10 psia and not greater than about 800 psia;

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switching the four-way valve to the startup position;
opening the isolation valve;
introducing fluid into the fluid processor at line pressure;
switching on the heater;
allowing steam generated by the heater to flow downstream of the reactor and exit
at a fluid outlet; and

switching the four-way valve to the normal position.

28. (original) A method for sanitizing the fluid processor of claim 24 during shutdown and storage, the method comprising:

turning off the pump and heater;
closing the isolation valve;
allowing residual heat of the reactor to produce steam from the fluid in the processor
assembly;
allowing the steam to generate a pressure in the processor assembly;
allowing the pressure to expel the fluid that is downstream of the processor assembly
out through a fluid outlet;
opening the drain valve to discharge the fluid that is upstream of the processor
assembly;
attaching a closure means to the fluid outlet when fluid ceases to flow from the fluid
outlet; and
closing the drain valve when the fluid ceases to flow from the drain valve.

29. (original) The method of claim 28, wherein the closure means is a container holding

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a sterile solution.

30. (previously presented) The method of claim 28, wherein the closure means is a filter.

31. (withdrawn-currently amended) The fluid processor of claim ~~[[23]]~~ 24, wherein the heat exchanger is a shell-and-tube heat exchanger and further, wherein a process fluid flows through a shell side of the heat exchanger and a product fluid flows through a tube side of the heat exchanger.

32. (currently amended) The fluid processor of claim ~~[[23]]~~ 24, wherein the heat exchanger is a tube-in-tube heat exchanger and further, wherein a process fluid flows through an annular side of the heat exchanger and a product fluid flows through a tube side of the heat exchanger.

33. (original) The fluid processor of claim 32, wherein the heat exchanger is a helical coil tube-in-tube heat exchanger.

34. (original) The fluid processor of claim 33, wherein the reactor and the heater are nested within the heat exchanger.

35. (original) The fluid processor of claim 34, wherein the reactor and the heater are disposed within a temperature homogenizer.

36. (withdrawn) The fluid processor of claim 35, wherein the temperature homogenizer comprises a multiplicity of blocks, the blocks being joined together by fasteners.

37. (original) The fluid processor of claim 35, wherein the temperature homogenizer is a unitary structure produced by casting and further, wherein the reactor is formed as an integral part of the temperature homogenizer.

38. (original) The fluid processor of claim 35, wherein the temperature homogenizer is

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enclosed by an insulation jacket.

39. (cancelled)

40. (cancelled)

41. (cancelled)

42. (cancelled)

43. (cancelled)

44. (cancelled)

45. (withdrawn-currently amended) The fluid processor of claim [[1]] 78, wherein the heater is a hot gas heater and further, wherein the processor assembly further comprises:

a helical coil tube-in-tube heat exchanger for exchanging heat between a process fluid and a product fluid; and

a helical coil-shaped reactor nested within the heat exchanger ~~for processing the process fluid to the product fluid by heating; and~~

~~a hot gas heater for heating the reactor.~~

46. (withdrawn) The fluid processor of claim 45, wherein the processor assembly further comprises an insulated duct having a hot gas inlet at one end and a vent at the other end and further, wherein the heat exchanger is disposed within the insulated duct.

47. (withdrawn) The fluid processor of claim 45, wherein the processor assembly further comprises a hot gas tube and an insulated enclosure having an opening at the top and further, wherein the heat exchanger is disposed within the enclosure and the reactor is disposed within the hot gas tube and further, wherein the hot gas tube is nested within the heat exchanger.

48. (withdrawn-currently amended) The fluid processor of claim [[1]] 78, wherein the

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processor assembly further comprises a multiplicity of heat exchangers for exchanging heat between a process fluid and a product fluid.

49. (withdrawn) The fluid processor of claim 48, wherein at least two heat exchangers are connected together in parallel.

50. (withdrawn) The fluid processor of claim 48, wherein at least two heat exchangers are connected together in series.

51. (withdrawn) The fluid processor of claim 48, wherein at least one heat exchanger is a tube-in-tube type heat exchanger.

52. (withdrawn) The fluid processor of claim 48, wherein at least one heat exchanger is a helical coil tube-in-tube type heat exchanger.

53. (withdrawn) The fluid processor of claim 48, wherein at least one heat exchanger is a rope rug coil tube-in-tube heat exchanger.

54-72 (cancelled)

73. (withdrawn) The fluid processor of claim 19, wherein the endotoxin sensor is disposed along a sampling line.

74. (withdrawn) The fluid processor of claim 1 further comprising:
a temperature sensor for measuring the temperature of the fluid upstream of the processor assembly.

75. (withdrawn) The fluid processor of claim 1 further comprising:
a temperature sensor for measuring the temperature of the fluid downstream of the processor assembly.

76. (withdrawn) The fluid processor of claim 1 further comprising:

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a pressure sensor for measuring the pressure of the fluid upstream of the processor assembly.

77. (withdrawn) The fluid processor of claim 1 further comprising:

a pressure sensor for measuring the pressure of the fluid downstream of the processor assembly.

78. (currently amended) A fluid processor comprising:

a pump for drawing a fluid from a fluid source through a fluid inlet and pressurizing the fluid;

a processor assembly comprising a fluid heater for processing heating the fluid from the pump;

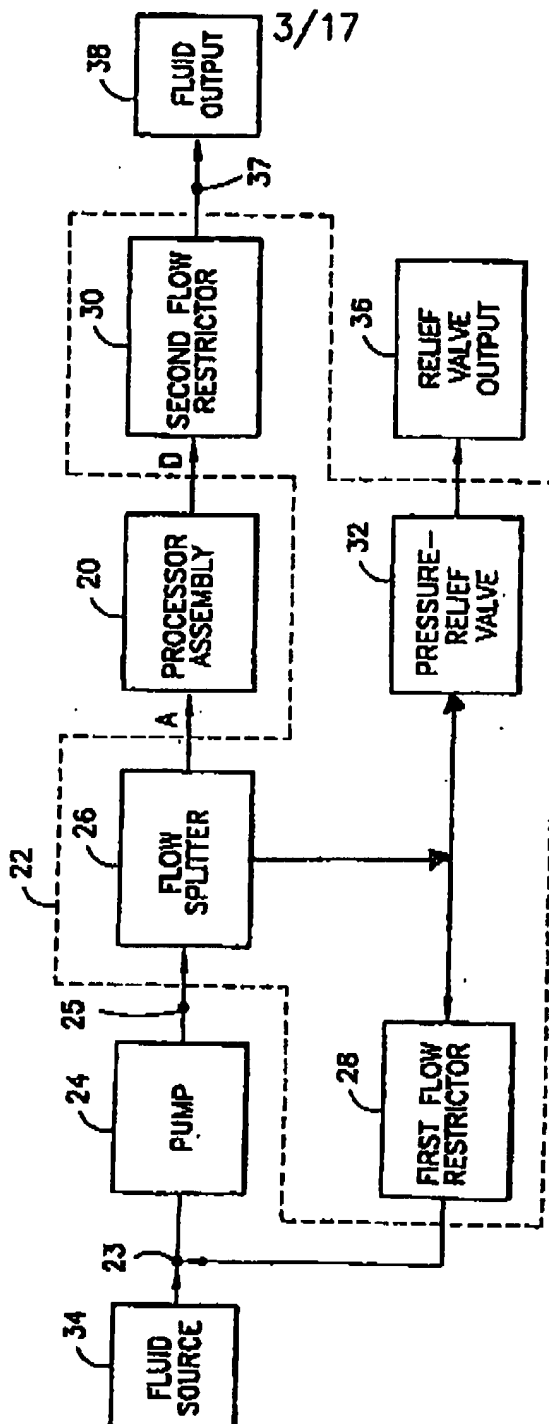
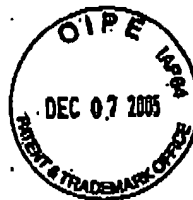
a process control system comprising: a flow splitter disposed between the pump and the processor assembly for diverting a portion of the fluid from the pump, a first flow restrictor for receiving the diverted fluid and directing the diverted fluid to the fluid inlet, a first pressure relief valve disposed between the first flow restrictor and the flow splitter, a second pressure relief valve disposed between an upstream side of the processor assembly and a downstream side of the flow splitter and a second flow restrictor disposed downstream of the processor assembly,

wherein the flow splitter, flow restrictors and pressure relief valves are constructed and arranged to coact with each other to control the pressure and flow rate of the fluid in the fluid processor.

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79. (previously presented) The fluid processor of claim 78, wherein the process control system further comprises a third pressure relief valve disposed downstream of the second flow restrictor.

REPLACEMENT SHEET



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OKay to enter. 1942

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